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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,960	05/02/2001	Susan E. Swift	A-69332-1/RMS/JJD	6153

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

BYRD, DEVON R

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,960

Applicant(s)

SWIFT ET AL.

Examiner

Devon R Byrd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 14-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig alpha-1, classified in class 435, subclass dig 2.
- II. Claims 1-5, 7, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig alpha-2, classified in class 435, subclass dig 2.
- III. Claims 1-5, 8, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig epsilon, classified in class 435, subclass dig 2.
- IV. Claims 1-5, 9, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-1, classified in class 435, subclass dig 2.
- V. Claims 1-5, 10, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-2, classified in class 435, subclass dig 2.
- VI. Claims 1-5, 11, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-3, classified in class 435, subclass dig 2.

- VII. Claims 1-5, 12, 13-16, 18, 19-21, 22, and 23 drawn to a method of screening candidate agents that modulate germline transcription of Ig gamma-4, classified in class 435, subclass dig 2.
- VIII. Claim 17, drawn to a method of screening for candidate agents comprising administering at least two separate probes, classified in class 435, subclass dig 2.
- IX. Claim 24, drawn to a method of quantifying the amount of germline constructs, classified in class 435, subclass 4.
- X. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig α 1 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.
- XI. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig α 2 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.
- XII. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig-epsilon, as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.
- XIII. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-1 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.
- XIV. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-2 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.

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XV. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-3 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.

XVI. Claims 25 and 26, drawn to kits for quantifying germline mRNA, specifically Ig gamma-4 as set forth in Figures 3A-3B and 4A-4B (SEQ ID NOS:1-13), classified in class 435, subclass 810.

NOTE: Claims 1-5, 13-16, and 18-23 are listed in multiple groups since said claims were found to be generic to Groups I-VII. Upon election of a single group, said claims will be examined according to the limitations of the elected group. Further, claims 25 and 26 are also listed in multiple groups, as said claims were found to be generic to Groups X-XVI. Upon election of a single group, said claims will be examined according to the limitations of the selected group.

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-VII are drawn to using materially distinct probes directed to distinct targets, e.g, Ig alpha-2, Ig epsilon, Ig gamma-2, etc.

Inventions I-VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups I-VII and VIII are drawn to using materially distinct and mutually exclusive methods yielding distinct products. Practicing a method of using a single probe directed to protecting Ig alpha-1 will not yield the same product as would using two probes, one

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directed to protecting Ig alpha-1 and a second probe directed to protecting Ig alpha-2, Ig epsilon, or Ig gamma-2, etc.

Inventions I-VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-VII and IX are drawn to using materially distinct and mutually exclusive methods yielding distinct products. Practicing a method of using a single probe directed to protecting Ig alpha-1 will not yield the same product as would using three probes, one directed to protecting Ig alpha-1 and a second probe directed to protecting Ig alpha-2, and a third directed to protecting Ig epsilon, or Ig gamma-2, etc.

Inventions X-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups X-XVI are drawn to using materially distinct probes directed to distinct targets, e.g., Ig alpha-2, Ig epsilon, Ig gamma-2, etc.

Inventions I-VII and X-XVI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Groups I-VII are drawn to a method of screening for agents capable of transcription modulation, whereas Group X-XVI is drawn to a kit for mRNA quantitation. The

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subcombination has separate utility such as screening for compounds that modulate transcription in non-germline cells or mRNA quantitation in non-germline mRNA samples.

Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups VIII and IX are drawn to using materially distinct and mutually exclusive methods yielding distinct products. Practicing a method of using two probes directed to protecting Ig alpha-1 will not yield the same product as would using three probes, one directed to protecting Ig alpha-1 and a second probe directed to protecting Ig alpha-2, and a third directed to protecting Ig epsilon, or Ig gamma-2, etc.

Inventions VIII and X-XVI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because while Group VIII is drawn to a method of screening for agents capable of transcription modulation, Group X-XVI is drawn to a kit for mRNA quantitation. The subcombination has separate utility such as screening for compounds that modulate transcription in non-germline cells or mRNA quantitation in non-germline mRNA samples.

Inventions IX and X-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

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different inventions of Groups IX and X-XVI are drawn to using materially distinct and mutually exclusive methods yielding distinct products. Practicing a method of using at least three probes will not yield the same product as a method using only one or two probes. Even if the methods of Groups IX and X were practiced with an equivalent number of probes, there is no requirement that they be the same three probes. Thus, the methods of Groups IX and X-XVI may have materially different operational parameters and outcomes.

If Group IX is elected, applicant must then elect three members of SEQ ID Nos 1-13 and further, elect one sequence therefrom for preliminary examination.

This application contains claims directed to the following patentably distinct species of the claimed invention: claim 18, drawn to small molecules; claims 19-21, drawn to peptides; and claims 22 and 23, drawn to retroviruses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devon R Byrd whose telephone number is 703-305-0159. The examiner can normally be reached on Mon-Fri 8a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-2317. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DB
June 30, 2003


ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600